REMARKS

For clarity and completeness, the office action (pp. 2,3, and 4(?)) is set forth in italics below, with remarks interspersed .

Application Control Number: 09/841546
Art Unit: 3737
The Substitute Specification filed 07-02-01 has been entered to the record

Claim Rejections - 35 USC,§ 112

l. .The following is a quotation of the second paragraph of 35 U. S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 32 - 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 32, the language expressing a range of per cents of 'conventional dosage' is vague and indefinite insofar as individual patients vary widely in weight and sensitivity and side effects to such vasodilatory drugs that a 'conventional dosage' is not a definite term unless referenced to some standard

The term "conventional dosage" has been deleted and the range from subclaim 34 substituted.

With respect to claim 35, it is unclear what constitute 'Nitroglycerin equivalents', moreover parenthesized terms within claims are understood to be non-limiting. Returning to the former point, specification page 5 lines 4 - 7 defines certain such equivalents. Thereafter a broad variety of drugs are recited up to page 7 line 15 which references an additional appendix. Yet it is unclear if these are 'Nitroglycerin equivalents' in applicant's art-defined sense or if applicant is preferring that all of these listed medications are patent language equivalents for purposes of claims construal.

"Nitroglycerin equivalent" is a dosage of a chosen vasodilator which dilates to the same extent as a dosage of nitroglycerin within the range stated. The parenthetical expression was merely a trademark for the generic term. The trademark has been removed without prejudice to the generic term.

With respect to claims 36 and 37 the claims scope is wholly unclear. This case originally contained only claims 1 - 20, all cancelled per instructions in the Preliminary Amendment filed [Page2]

The Substitute Specification filed 07-02-01 has been entered to the record April 23, 2001 to cancel all prior claims. Therefore there is no claim 21 and no claim construable as being the parent claim to these claims for purposes of understanding their method scope

References to Claim 21 have been replaced with references to Claim 32.

With respect to claim 38, the preamble pertains to a 'titration system' whereas the body of the claim recites only method steps non-limiting on the titration system hence the scope is wholly unclear.
[Page 3]

The method words have been deleted and Claim 38 now reads as an apparatus claim.

Claim Rejections - 35 USC §103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
4. Claims 32 - 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panoz (US4592753) in view of Stanley et al (US4885173). The former teaches the use of a patch (col. 1 lines 33 - 68) of 2% nitroglycerin or clonidine transdermal delivery system for administration of these vasodilatory agents (col. 4 lines 7-13) including treatment of systemic diseases such as hypertension. It would have been obvious to provide usage/dosage instructions with a potent prescription drug, and for example user instructions are provided, see col. 2 lines 22 - 24 and 5 lines 14 - l 6 .It would have been obvious in view of Stanley et at cols.5 - 6 and col. 8 lines 29 – 37 to titrate a vasodilator dosage in view of the patent's statements and side-effects stated. [Page 2]

Panoz (US4592753) does teach the use of a patch (col.1 lines 33 - 68) of 2% nitroglycerin or clonidine transdermal delivery system for administration of these vasodilatory agents (col. 4 lines 7-13) including treatment of *angina* with nitroglycerin (col. 4, lines 7-9) and hypertension with *clondine* col. 4 line 11).

Panoz does not mention dosage, but clearly intends to provide the conventional nitroglycerin dosage for angina, because Panoz is directed to an improved patch, not to improved treatment of a particular disease. Panoz is not directed "for treatment of diseases involving vasospasm" as recited in the present claims. Thus Panoz teaches nothing regarding treatment of the diseases recited in the present claims, nor the reduced dosages discovered to be effective for such diseases, much less the concept of measuring blood flow to test for vasospasm, still much less the device for applying reduced dosage in response to such blood flow tests over time. In short, Panoz is not trying to solve the problem solved by the invention.

Adding Stanley does not cure the defects of Panoz. Stanley et al (US4885173) at cols.5-6 and col. 8 lines 29-37 merely teaches one to let a patient lick a medicated lollipop to administer a vasodilator dosage in view of the *patent's statements* and side-effects stated. If patents subjectively knew when they suffered vasospasms, there would be no need for the objective flow testing which is a fundamental feature of the invention, recited in the claims. Applicant has discovered that an objective test (not

subjective statements) must be used to titrate dosage to achieve the valuable cures described in the Examples.
A person who read Panoz and who somehow choose to also read Stanley would still not learn how to achieve the valuable results shown in the many Examples of the Application, because the combination of testing apparatus and controlled dosage over time is not taught by either reference, alone or combined.

The Substitute Specification filed 07-02-01 has been entered to the record.
The Examiner is thanked for entering the substitute specification.

Renumbering of claims in consecutive order per Rule 126 has been held in abeyance pending understanding of status of claims 21 -31 and antecedent reference made to claim 21 in the current claims.
The reference to "Claim 21" has been deleted.

1. Any inquiry concerning this communication should be directed to Examiner Francis J. Jaworski at telephone number 703-308-3061
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Conclusion

Panoz teaches nothing regarding titration and Stanley teaches nothing regarding curing strokes, and the combination of these references would not make the present invention obvious. See, for example, Equipment Co. v. United States, 702 F.2d 1005, 217 U.S.P.Q. 193
(Fed. Cir. 1983):

> The question of nonobviousness is a simple one to ask, but difficult to answer . . . The difficulty which attaches to all honest attempts to answer this question can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness.

No estoppel has been created by these amendments. See Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc., 230 U.S.P.Q. 45 (Fed. Cir. 1986) (where a patentee's amendments were not required in response to an examiner's rejection, or critical to the allowance of the claims, no estoppel has been found)

citing, Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 28 U.S.P.Q. 356 (Fed. Cir. 1986) and Datascope Corp. v. SMEC, Inc., 776 F.2d 320, 227 U.S.P.Q. 838 (Fed. Cir. 1985). See also, Insta-Foam Products Inc. v. Universal Foam Systems, Inc, 15 U.S.P.Q.2d 1295 (Fed. Cir. 1990).

A Notice of Allowance is earnestly solicited.

Any (small entity) charges required for the prosecution of this application should henceforth be charged to USPTO Deposit Account 20-0336 of Technology Licensing Co. LLC.

Please note the address and telecontact numbers and direct all future correspondence to that address.

Please advise if anything further is required at this time.

Respectfully submitted,

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Paper No.

Notice of Non-Compliant Amendment (Voluntary Revised Practice)

The amendment filed 4-25-03 under the voluntary revised amendment practice guidelines[1], published in the Official Gazette on February 25, 2003 (*Amendments in a Revised Format Now Permitted,* 1267 Off. Gazette 106), does not fully comply with minimal requirements of the voluntary practice. In order for the amendment to be entered, it must either (1) comply with the guidelines of the voluntary revised amendment practice (which practice invokes waivers of certain 37 CFR 1.121(a)-(d) requirements) or (2) comply with current 37 CFR 1.121 requirements.

THE FOLLOWING ITEM(S) IN APPLICANT'S AMENDMENT CAUSES THE AMENDMENT TO BE NON-COMPLIANT WITH THE VOLUNTARY REVISED AMENDMENT PRACTICE.

☒ 1. A complete listing of all of the claims is not present in the amendment paper.

☐ 2. The listing of claims does not include the text of all claims currently under examination.

☒ 3. The claims of this amendment paper have not been presented in ascending numerical order.

☐ 4. Each claim has not been provided with a status identifier, and, as such, the individual status of each claim cannot be determined.

☐ 5. Other: _____

_____

_____

LIE: Check one of the following boxes:

☐ **PRELIMINARY AMENDMENT:** Applicant is given ONE MONTH from the mail date of this letter to re-submit the amendment in compliance with either the guidelines of the revised amendment practice or current 37 CFR 1.121. Failure to comply with either the current 37 CFR 1.121 practice or with the voluntary practice will result in non-entry of the amendment and examination on the merits will commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.

☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above-mentioned reply appears to be a *bona fide* response, applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit an amendment which complies with either the voluntary practice guidelines or current 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).

Valerie Douglas
Supervisory Legal Instruments Examiner (SLIE)

[1] For further explanation of the guidelines of the revised amendment format, please see the posted notice and sample amendment format at:
http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf and
http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/formntrevamdtprac.pdf

March 18, 2003